



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor Application of:
Jack Roth *et al.*

Serial No.: 10/784,538

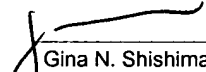
Filed: February 23, 2004

For: METHODS AND COMPOSITIONS
COMPRISING DNA DAMAGING
AGENTS AND p53

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: INRP:050USC1

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
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April 14, 2004	
Date	Gina N. Shishima

INFORMATION DISCLOSURE STATEMENT

MS DD

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INRP:050USC1.

This application is a continuation application of Serial No. 08/233,002, filed April 25, 1994, now issued as Patent No. 5,747,496, and is relied upon for an earlier filing date under 35 U.S.C. § 120. Serial No. 08/918,407, filed March 6, 1991, is an application that has been allowed and claims priority to the same parent application. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 08/233,022.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Date: April 14, 2004



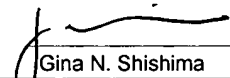
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MS DD

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 10/784,538 entitled "METHODS AND COMPOSITIONS COMPRISING DNA DAMAGING AGENTS AND p53" – Jack Roth et al.*
Our reference: INRP:050USC1
Client reference: MDA90-002

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, and Form PTO-1449.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INRP:050USC1.

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Respectfully submitted,



Gina N. Shishima
Reg. No. 45,104

GNS/kmv
Encl.: as noted

Form PTO-1449 (modified)

Atty. Docket No.

Serial No.

INRP:050USC1

10/784,538

List of Patents and Publications for Applicant's

Applicant

Jack Roth *et al.*

INFORMATION DISCLOSURE STATEMENT

Filing Date:

February 23, 2004

Group:

Unknown

(Use several sheets if necessary)

U.S. Patent Documents

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Foreign Patent Documents

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Other Art

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U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	4,740,463	04/26/88	Weinberg <i>et al.</i>			
	A2	4,920,209	4/24/90	Davis <i>et al.</i>	435	235	
	A3	4,980,289	12/25/90	Temin <i>et al.</i>			
	A4	5,055,400	10/08/91	Lo <i>et al.</i>			
	A5	5,166,320	11/24/92	Wu <i>et al.</i>			
	A6	5,252,479	10/12/93	Srivastava			
	A7	5,328,470	07/12/94	Nabel <i>et al.</i>			
	A8	5,362,623	11/08/94	Vogelstein <i>et al.</i>	435	6	
	A9	5,496,731	3/5/96	Xu, <i>et al.</i>	435	320.1	
	A10	5,527,676	6/18/96	Vogelstein <i>et al.</i>	435	6	
	A11	5,532,220	07/02/96	Lee <i>et al.</i>			
	A12	5,585,362	12/17/96	Wilson <i>et al.</i>	514	44	
	A13	5,747,469	05/05/98	Roth <i>et al.</i>			
	A14	5,932,210	8/3/99	Gregory <i>et al.</i>	424	93.2	
	A15	6,090,566	07/18/00	Vogelstein <i>et al.</i>	435	7.23	

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	* 04-009338	1/14/92	Japan			
	B2	* 8-508879	9/24/96	Japan			
	B3	* EP 0174608	09/05/85	Europe			
	B4	* EP 0351585	06/23/89	Europe			
	B5	* EP 0390323	10/03/90	Europe			

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EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. INRP:050USC1	Serial No. 10/784,538
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Jack Roth <i>et al.</i>	
		Filing Date: February 23, 2004	Group: Unknown
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

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	B6	X EP 0475623	08/23/91	Europe			
	B7	X FR 2688514	09/17/93	France			
	B8	X WO 90/05180	5/17/90	PCT			
	B9	X WO 90/10448	09/29/90	PCT			
	B10	X WO 91/15580	10/17/91	PCT			
	B11	X WO 93/03769	03/04/93	PCT			
	B12	X WO 93/19191	9/30/93	PCT			
	B13	X WO 93/25224	12/23/93	PCT			
	B14	X WO 94/06910	3/31/94	PCT			
	B15	X WO 94/08026	04/14/94	PCT			
	B16	X WO 94/10323	05/11/94	PCT			
	B17	X WO 94/18992	9/1/94	PCT			
	B18	X WO 94/24297	10/27/94	PCT			
	B19	X WO 94/26914	11/24/94	PCT			
	B20	X WO 95/02697	01/26/95	PCT			
	B21	X WO 95/11301	4/27/95	PCT			
	B22	X WO 95/11984	5/4/95	PCT			
	B23	X WO 95/14101	5/26/95	PCT			
	B24	X WO 95/14102	5/26/95	PCT			
	B25	X WO 95/23867	9/8/95	PCT			
	B26	X WO 95/30002	11/09/95	PCT			

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1 *	Anderson, "Human Gene Therapy," <i>Nature</i> , 392:25-30, April 30, 1998.
	C2 *	Bacchetti <i>et al.</i> , "Inhibition of cell proliferation by an adenovirus vector expressing the human wild type p53 protein," <i>Int. J. Oncol.</i> , 3(5):781-788, 1993.
	C3 *	Baker <i>et al.</i> , "Suppression of human colorectal carcinoma cell growth by wild-type p53", <i>Science</i> , 249:912-915, 1990.
	C4 *	Baker <i>et al.</i> , "p53 Gene Mutations Occur in Combination with 17p Allelic Deletions as Late Events in Colorectal Tumorigenesis," <i>Cancer Research</i> , 50:7717-7722, December 1990.
	C5 *	Bandyopadhyay and Temin, "Expression of complete chicken thymidine kinsase gene inserted in a tetrovirus vector," <i>Mol. Cell. Biol.</i> , 4(4):749-754, 1984.
	C6 *	Bargonetti <i>et al.</i> , "Wild-type but not mutant p53 immunopurified proteins bind to sequences adjacent to the SV40 origin of replication," <i>Cell</i> , 65:1083-1091, 1991.
	C7 *	Berkner, "Development of adenovirus vectors for the expression of heterologous genes", <i>BioTechniques</i> , 6(7):616-629, 1988.
	C8 *	Blenis, "Signal transduction via the MAP kinases: Proceed at your own RISK", <i>Proc. Natl. Acad. Sci. USA</i> , 90:5889-5892, 1993.
	C9 *	Bowtell <i>et al.</i> , "Comparison of expression in hemopoietic cells by retroviral vectors carrying two genes," <i>J. Virol.</i> , 62(7):2464-2473, 1988.
	C10 *	Brachman <i>et al.</i> , "p53 mutation does not correlate with radiosensitivity in 24 head and neck cancer cell lines", <i>Cancer Res.</i> , 53:3667-3669, 1993.
	C11 *	Brown <i>et al.</i> , "Increased accumulation of p53 protein in cisplatin-resistant ovarian cell lines," <i>Int. J. Cancer</i> , 55:678-684, 1993.
	C12 *	Brown <i>et al.</i> , "Mutant p53 confers cisplatin-sensitivity to resistant ovarian tumour cells with elevated wild-type p53," <i>Proc. Am. Assoc. Cancer Res.</i> , 34:355, Abstract #2116, 1993.
	C13 *	Cai <i>et al.</i> , "Stable expression of the wild-type p53 gene in human lung cancer cells after retrovirus-mediated gene transfer," <i>Hum. Gene Ther.</i> , 4:617-24, 1993.
	C14 *	Capecchi, "Altering the genome by homologous recombination", <i>Science</i> , 244:1288-1292, 1989.
	C15 *	Carter <i>et al.</i> , "Adenovirus Containing a Deletion of the Early Region 2A Gene Allows Growth of Adeno-Associated Virus with Decreased Efficiency," <i>Virology</i> , 191:473-476, 1992.

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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C16 *	Casey <i>et al.</i> , "Growth suppression of human breast cancer cells by the introduction of a wild-type p53 gene," <i>Oncogene</i> , 6:1791-1797, 1991.
	C17 *	Casson <i>et al.</i> , "p53 gene mutations in Barrett's epithelium and esophageal cancer," <i>Cancer Res.</i> , 51:4495-4499, 1991.
	C18 *	Chang <i>et al.</i> , "Inhibition of intratracheal lung cancer development by systemic delivery of E1A," <i>Oncogene</i> , 13:1405-1412, 1996.
	C19 *	Chang <i>et al.</i> , "Restoration of the G1 Checkpoint and the Apoptotic Pathway Mediated by Wild-type p53 Sensitizes Squamous Cell Carcinoma of the Head and Neck to Radiotherapy," <i>Arch Otolaryngol Head Neck Surg.</i> , 123:507-512, 1997.
	C20 *	Chen <i>et al.</i> , "Expression of wild-type p53 in human A673 cells suppresses tumorigenicity but not growth rate," <i>Oncogene</i> , 6:1799-1805, 1991.
	C21 *	Chen <i>et al.</i> , "Genetic mechanisms of tumor suppression by the human p53 gene," <i>Science</i> , 250:1576-1580, 1990.
	C22 *	Cheng <i>et al.</i> , "Suppression of acute lymphoblastic leukemia by the human wild-type p53 gene," <i>Cancer Res.</i> , 52:222-226, 1992.
	C23 *	Clarke <i>et al.</i> , "Thymocyte apoptosis induced by p53-dependent and independent pathways," <i>Nature</i> , 362:849-852, 1993.
	C24 *	Coleman <i>et al.</i> , "Radiation and chemotherapy sensitizers and protectors", <i>Critical Reviews In Oncology/Hematology</i> , 10(Issue 3):225-252, 1990.
	C25 *	Colicos <i>et al.</i> , "Construction of a recombinant adenovirus containing the <i>denV</i> gene from bacteriophage T4 which can partially restore the DNA repair deficiency in xeroderma pigmentosum fibroblasts," <i>Carcinogenesis</i> , 12(2):249-255, 1991.
	C26 *	Comings, "A general theory of carcinogenesis," <i>Proc. Natl. Acad. Sci. USA</i> , 70(12-Part I):3324-3328, 1973.
	C27 *	Conroy, "New gene therapy cleared for use against lung cancer," <i>Biotech Daily</i> , pp. 3-4, 1992.
	C28 *	Co-pending U.S. Patent Application Serial No. 07,665,538, filed March 6, 1991 (UTSC:171).
	C29 *	Co-pending U.S. Patent Application Serial No. 08/145,826, filed October 29, 1993 (INRP:005).
	C30 *	Copies of slides from presentation by Jack A. Roth on September 19, 1996.

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		<i>NO. RECEIVED</i>
	C31 *	Crown <i>et al.</i> , "High-intensity chemotherapy with hematopoietic support in breast cancer," <i>Annals of the New York Academy of Sciences</i> , 698:378-388, 1993.
	C32 *	Culver <i>et al.</i> , "In vivo gene transfer with retroviral vector-producer cells for treatment of experimental brain tumors", <i>Science</i> , 256:1550-1552, 1992.
	C33 *	Cureil <i>et al.</i> , "High-efficiency gene transfer mediated by adenovirus coupled to DNA-polylysine complexes," <i>Human Gene Therapy</i> , 3:147-154, 1992.
	C34 *	Davidson <i>et al.</i> , "A model system for in vivo gene transfer into the central nervous system using adenoviral vector," <i>Nature Genetics</i> , 3:219-223, 1993.
	C35 *	Debus <i>et al.</i> , <i>J. Cancer Res. Clin. Oncol.</i> , 116(Suppl Part 1):5-162, Abstract # A2.037.09, 1990.
	C36 *	Delauney <i>et al.</i> , "A stable bifunctional antisense transcript inhibiting gene expression in transgenic plants," <i>Proc. Natl. Acad. Sci. USA</i> , 85:4300-4304, 1988.
	C37 *	Dialog Search Report dated September 22, 1992.
	C38	Dialog Search Reports dated August 7, 1992 and February 26, 1993.
	C39 *	Diller <i>et al.</i> , "p53 functions as a cell cycle control protein in osteosarcomas," <i>Molec. Cell. Biol.</i> , 10(11):5772-5781, 1990.
	C40 *	Donehower, "Tumor suppressor gene p53 and apoptosis," <i>Cancer Bull.</i> , 46(2):161-166, 1994.
	C41 *	Dorigo <i>et al.</i> , "Sensitization of rat glioblastoma multiforme to cisplatin in vivo following restoration of wild-type p53 function," <i>J. Neurosurg.</i> , 88:535-540, 1998.
	C42 *	Eaves <i>et al.</i> , "The biology of normal and neoplastic stem cells in CML," Chronic Myeloid Leukemia, 2 nd Int'l Conference, Bologna, Italy, October 4-7, 1992. From <i>Leukemia and Lymphoma</i> , 11:245-253 (1993).
	C43 *	El Rouby <i>et al.</i> , "p53 gene mutation in B-cell chronic lymphocytic leukemia is associated with drug resistance and is independent of MDR1/MDR3 gene expression," <i>Blood</i> , 82(11):3452-3459, 1993.
	C44 *	El-Deiry <i>et al.</i> , "WAF1, a potential mediator of p53 tumor suppression," <i>Cell</i> , 75:817-825, 1993.
	C45 *	Eliyahu <i>et al.</i> , "p53 - A potential suppressor gene?" <i>J. Cell. Biochem.</i> , UCLA Symposia on Molecular and Cellular Biology, Abstracts, 19 th Annual Meeting, Supplement 14C:264, #I 030, 1990.

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Exam. Init.	Ref. Des.	Citation
	C46 *	Eliyahu <i>et al.</i> , "Meth A Fibrosarcoma Cells Express Two Transforming Mutant p53 Species," <i>Oncogene</i> , 3:313-321, 1988.
	C47 *	Eliyahu <i>et al.</i> , "Wild-type p53 Can Inhibit Oncogene-Mediated Focus Formation," <i>Proc. Nat. Acad. Sci. USA</i> , 85:8763-8767, November 1989.
	C48 *	Fan <i>et al.</i> , "p53 gene mutations are associated with decreased sensitivity of human lymphoma cells to DNA damaging agents," <i>Cancer Res.</i> , 54(22):5824-5830, 1994.
	C49 *	Fan <i>et al.</i> , "The role of p53 in cell cycle arrest and apoptosis induced by multiple chemotherapeutic agents in Burkitt's lymphoma cells," <i>Proc. Am. Assoc. Cancer Res.</i> , 35:311, Abstract #1851, 1994.
	C50 *	Federal Register, 47(56):pp. Title - VI and i-iv, March 23, 1982.
	C51 *	Feig <i>et al.</i> , "Somatic activation of <i>ras</i> ^K gene in a human ovarian carcinoma", <i>Science</i> , 223:698-701, 1984.
	C52 *	Felgner <i>et al.</i> , "Lipfection: a highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> , 84:7413-7417, 1987.
	C53 *	Finkel <i>et al.</i> , "Activation of <i>ras</i> genes in human tumors does not affect localization, modification, or nucleotide binding properties of p21", <i>Cell</i> , 37:151-158, 1984.
	C54 *	Finlay <i>et al.</i> , "The p53 Proto-Oncogene Can Act as a Suppressor of Transformation," <i>Cell</i> , 57:1083-1093, June 1989.
	C55 *	Foreman <i>et al.</i> , <i>Bone Marrow Transport</i> , 4(3), 1990.
	C56 *	Fornace, Jr. "Induction by radiation of mammalian genes associated with growth-arrest and apoptosis, and the role for the p53 tumor suppressor in their regulation," <i>Proc. Am. Assoc. Cancer Res.</i> , 35:681-682, 1994.
	C57 *	Fox, "Investigation of gene therapy begins," <i>Nature Biotechnology</i> , 18:143-144, 2000.
	C58 *	Friedmann, "Gene therapy of cancer through restoration of tumor-suppressor functions?," <i>Cancer Suppl.</i> , 70(6):1810-1817, 1992.
	C59 *	Fritsche <i>et al.</i> , "Inhibition of cell proliferation by an adenovirus vector expressing the human wild type p53 protein," <i>Int. J. Oncology</i> , 3:781-785, 1993.

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	C60 *	Fritsche <i>et al.</i> , "Induction of nuclear accumulation of the tumor-suppressor protein p53 by DNA-damaging agents," published erratum, <i>Oncogene</i> , 8(9):2605, 1993.
	C61 *	Fujiwara <i>et al.</i> , "Induction of chemosensitivity in human lung cancer cells <i>in vivo</i> by adenovirus-mediated transfer of the wild-type p53 gene," <i>Cancer Res.</i> , 54:2287-2291, 1994.
	C62 *	Fujiwara <i>et al.</i> , "Induction of chemosensitivity in human lung cancer cells <i>in vivo</i> by adenovirus-mediated transfer of the wild-type p53 gene," <i>Surgical Forum</i> , 45:524-526, 1994.
	C63 *	Fujiwara <i>et al.</i> , "A retroviral wild-type p53 expression vector penetrates human lung cancer spheroids and inhibits growth by inducing apoptosis," <i>Cancer Res.</i> , 53:4129-4133, 1993.
	C64 *	Fujiwara <i>et al.</i> , "Therapeutic effect of a retroviral wild-type p53 expression vector in an orthotopic lung cancer model," <i>J. Natl. Cancer Inst.</i> , 86(19):1458-1462, 1994.
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	C66 *	Georges, <i>et al.</i> , "Prevention of Orthotopic Human Lung Cancer Growth by Intratracheal Instillation of a Retroviral Antisense K-ras Construct," <i>Cancer Research</i> , 53:1743-1746, 1993.
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